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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/648,790	Applicant(s) Hartley et al.
	Examiner William Sandals	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Aug 28, 2000*

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1 and 52-67* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1 and 52-67* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [X] The drawing(s) filed on *Aug 28, 2000* is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)
16) [X] Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4, 5*
18) [ ] Interview Summary (PTO-413) Paper No(s). _____
19) [ ] Notice of Informal Patent Application (PTO-152)
20) [ ] Other:

DETAILED ACTION

Drawings

1. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to notification. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 52-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1 and 52-67 are drawn to the limitation "*in vitro* or *in vivo*". "*in vitro* or *in vivo*" is not defined in the instant specification. "*in vitro*" transposition is used in the prior art to mean a transposition reaction which is carried out in cells in a reaction vessel, as well as a transposition reaction carried out where the target nucleic acid and the transposase are not in cells in a reaction

vessel. Therefore one of skill in the art would not know the metes and bounds of "*in vitro* or *in vivo*". As a result the claim is vague and indefinite.

5. In claim 1, the term "product molecules" is used at lines 15, 17 and 29. The "product molecules" of lines 15 and 17 appear to be one and the same, while the "product molecules" of line 29 appear to be different. This conflict of usage makes the meaning of the claim vague and indefinite.

6. In claim 1, the term "vector donor" is used at lines 8, 14, 21 and 28. The "vector donor" of lines 8 and 14 appear to be one and the same, while the "vector donor" of lines 21 and 28 appear to be different. This conflict of usage makes the meaning of the claim vague and indefinite.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The term "recombination sites" is used in section "(a)" and again at section "(c)". The "recombination sites" of each of sections "(a)" and "(c)" are each recited that they do not recombine with each other. Nowhere in the claim does it state that any of the recombination sites will recombine, yet the outcome of the claim appears to require that the "recombination sites" be identical for the reaction to proceed as claimed. None of the "recombination sites" as claimed must be identical, making the method unclear as to what elements may be required for the practice of the invention. This internal inconsistency makes the meaning of the claim vague and indefinite.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The method requires that two nucleic acids be recombined at recombination sites. This outcome requires that the recombinase protein act on the recombination sites to perform the requisite recombination forming the product molecules. However, the claim as written does not require that the recombinase protein be involved in the reaction to produce the product molecules.

9. Claim 52 contains the trademark/trade name PCR. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymerase chain reaction and, accordingly, the identification/description is indefinite.

10. Claims 60, 62 and 64 recite the limitation "mutants thereof". One of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation. A mutation of a recombination site may be closely patterned after the subject recombination site or may be very loosely patterned after the subject recombination site, such that it may bear no resemblance or

form recognizable as the subject recombination site which may be chemically and/or biologically totally unrelated in function or form to the subject recombination site.

11. Claim 65 recites the limitation "said product nucleic acid molecule" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by US 5,851,808.

US 5,851,808 taught (see especially columns 7, 29 and the claims) a method for cloning or subcloning comprising combining a site specific recombination protein with an insert donor nucleic acid comprising a desired nucleic acid flanked by *loxP* and *loxP511* recombination sites and a first vector donor nucleic acid comprising *loxP* and *loxP511* recombination sites. US 5,851,808 taught that the *loxP* and *loxP511* recombination sites do not recombine with each other. The *loxP* site recombines with the *loxP* site and the *loxP511* site recombines with *loxP511* site in the insert donor nucleic acid and the first vector donor nucleic acid to produce a first product nucleic acid comprising the desired nucleic acid flanked by a *loxP* site and a *loxP511*

site. The first product nucleic acid is then combined with a recombination protein, a second vector donor nucleic acid where the second vector donor nucleic acid comprises a *loxP* site and a *loxP511* site. Recombination occurs between the *loxP* and *loxP* recombination sites, and *loxP511* and *loxP511* recombination sites respectively, and the first product nucleic acid and the second vector donor nucleic acid recombine to produce a second product nucleic acid comprising the desired nucleic acid flanked by a *loxP* site and a *loxP511* site.

14. Claims 52-57 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,851,808.

US 5,851,808 taught (see especially columns 7, 29 and the claims) an in vitro method of cloning a polymerase chain reaction product comprising obtaining a polymerase chain reaction product comprising a first recombination site and a second recombination site which do not recombine with each other and combining the polymerase chain reaction product with a vector comprising a third recombination site and a fourth recombination site which do not recombine with each other under conditions such that recombination occurs between the first and third recombination sites and the second and fourth recombination sites thereby making a product vector. The product vector may be inserted into a host cell. The vector may be an expression vector. The vector may contain a selectable marker, a cloning site, a restriction site, an operon, an origin of replication and a gene or a partial gene. The polymerase chain reaction product may be linear. The recombination sites may be *lox* sites, which may be *loxP* or *loxP511*, or *att* sites, or FRT sites. The recombination protein may be Cre.

US 5,851,808 did not teach that *att* sites may be *attB* sites, *attP* sites, *atttL* sites or *attR* sites, nor that the recombination *att* recombination proteins are Int Xis or IHF. However, it is well known in the art that *att* sites may be *attB* sites, *attP* sites, *atttL* sites or *attR* sites, and that the *att* recombination proteins are Int, Xis or IHF as taught in US 5,354,668 at columns 10-11.

Conclusion

15. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner

March 22, 2002